REMARKS

Claims 1-12, 26-34, 43, 44 and 63-73 are pending. Claims 10 and 11 are amended. Claims 64-73 are new claims.

Applicants acknowledge with appreciation the withdrawal of the finality of the Office Action mailed August 26, 2003, which indicated allowability of claims 10, 11, 26-34, 43 and 44. Presently, only claims 10 and 111 are allowed.

Responsive to the previous indication of finality and allowability, Applicants have cancelled claims1-9 and 12; said cancellation was done to expedite allowance of claims that were then indicated to be allowable; however, since the final rejection abrogates this reason for cancellation, the present amendment reinstates former claims 1-9 and 12, which are now presented as claims 64-73. Claims 10 and 11 have been amended to recite a "polypeptide."

The Office objects to claims 10 and 11 and suggests that amending "peptide" to – polypeptide – will overcome the objection. This has been done. The Office further suggests amending "mannanase A" to –ManA- to overcome a further objection. This also has been done.

Claims 26-34, 43-44 and 63 stand rejected under 35 U.S.C. §112, first paragraph because the specification is enabling for ManA having the sequence of SEQ ID NO: 1, is deemed not to be enabling for any such enzyme having the sequence identity as claimed. It is asserted that the specification does not provide a scope of enablement that is commensurate with the scope of the claims. We respectfully traverse.

The Office is responding as though Applicant has provided no rationale, guidance or representative compounds, when in fact the specification does contain a showing of enablement that is commensurate with the scope of the claims. Applicant has met the requirement, for example, by comparison of conserved residues where these residues are common structural features of claims genus (see Table 3 bridging 33 and 34 of the specification as filed). Furthermore, a great number of GH5, CBDII and CBDIII family domains are well known in the art. See the Declaration of Shi-You Ding filed in response to the Office Action dated January 10, 2003. It is apparent to those skilled in the art on the basis of the present disclosure that the process of comparison to deduce conserved residues may be repeated in the same manner shown and described. Applicant has characterized the

polypeptide sequence by domain or region in remarks, for example, on page 18 at lines 18-26. Applicant has provided guidance for making deletions or substitutions in a discussion on page 19 at lines 8-20, and has discussed suitable techniques including fusion proteins and site directed mutagenesis on page 20 of the specification.

Cases before the Court of Appeals for the Federal Circuit have considered what showing may be sufficient to meet a genus-type claim when a species is specifically enabled in the working examples. There is no need to show each and every possible embodiment. A representative number of species will suffice, as will sufficient rationale or guidance as in the present case.

The ultimate issue is whether undue experimentation is required. To establish this standard, the Office presently relies upon *In re Wands*, 8 USPD 2d 1400 (Fed. Cir. 1988) and so admits that a satisfactory showing may include: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented; (3) the present or absence of working examples; (4) the nature of the invention, (5) the state of the prior art. (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and the breadth of the claims. These rules are not applied in a vacuum. *In Wands*, the issue was the predictability of being able to make a particular monoclonal antibody. The court said:

Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not experimentation: . . . The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art. The test is not merely quantitative, since a considerable amount of the experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *Id.* At 1404.

In relevant art at the time this application was filed, the level of ordinary skill was quite high. It is also the case that routine experimentation in this art may encounter failures in addition to successes. Therefore, when applying the Wands "standard of reasonableness" to the situation in this art means it is not undue nor is it unexpected to encounter some failure.

The important point is that some experimentation is not undue for this art. Applicant has provided reasonable guidance and rationale for performing this type of work.

The Office finds that it is not routine in the art to modify an amino acid sequence when the results of such modification are unknown, and the success of such modification are unpredictable. We disagree and assert that it is routine in the art to make such modifications. If the examiner wishes to pursue this line of reasoning, it will be necessary for the examiner to provide a reference showing that it is not routine. Initially, the Office must accept the objective truth of statements made in the specification. If such statements are to be called into question, the Office is burdened with providing evidence or convincing argument why those of skill in the art would doubt the statements. *In re Marzocchi*, 439 F. 2d 220, 169 USPQ 367 (CCPA 1971). Applicant asserts that the Office has not met this burden.

The Office finds that the specification does not establish a variety of things to make the result of modifications predictable, such as the regions of the protein structure which may be modified without affecting mannanase activity, the general tolerance to mannanase to modification, or rationale and predictable scheme for modification. In response, we direct the examiner's attention to Table 3 and other portions of the specification that are noted in remarks above.

In summary, the foregoing remarks show the enablement is commensurate with the scope of the claims, and so we request withdrawal of the rejection.

Claims 26-27, 44 and 63 stand rejected under 35 USC §102(b) over Johnson et al. (1990). Although Johnson et al. does not disclose any sequence at all, the Office takes the position that it is ill-equipped to show a distinction between the reference and the present claims, and so shifts that burden to Applicant. The attached Declaration of William Adney shows this distinction. Mr. Adney has used the DSGene program to calculate a molecular weight of the disclosed ManA peptide. It is 80,349.9 Daltons. This compares to four mannanase enzymes reported by Johnson et al. These mannanases are shown in Table 2 on page 251 thereof to have respective molecular weights of 44,700, 43600, 57,500, and 33,900. These do not compare to 80,349, and the enzymes cannot be the same.

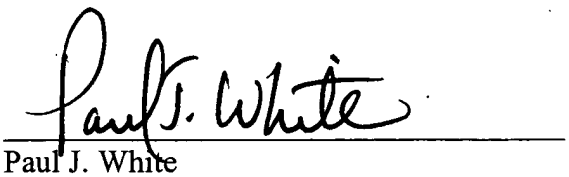
Applicant has met its showing, and the claims are not anticipated. We request withdrawal of the §102 rejection.

Claims 28-34, and 43 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Johnson et al. as applied above, and further in view of reasonable common knowledge regarding determining the amino acid sequence and making proteins with a peptide tag, such as a 6-His tag. The Office cannot have it both ways where no sequence is specifically enabled unless it is particularly shown (this is the enablement issue disposed above), and then also there is reasonable common knowledge of the type described. Even so, we tend to agree with the Examiner that there is reasonable common knowledge in this art which can adapted and applied to make new things. We diverge and disagree as to the present combination of reasonable knowledge with Johnson et al., because the sequences that are particularly claims are not suggested or taught by the combination and because Applicant has met the burden of showing that the Johnson et al. enzyme is very different from what is claimed.

In view of the Preliminary Amendment and foregoing discussions together with the fact that the objections in the Advisory Action are not ground in prior art, claims 1-12, 26-34, 43, 44 and 63-73 are now in condition for allowance and early notification of the same is earnestly solicited.

The Commissioner is authorized to charge any additional required fees to deposit account 14-0460. Should the Examiner have any questions, comments, or suggestions that would expedite the prosecution of the present case to allowance, Applicant' undersigned representative earnestly requests a telephone call at (303) 384-7575.

Respectfully submitted,



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